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Letter of confirmation

Nitrosamines in evaporated salt

Schweizer Salinen AG confirms that an internal risk assessment for a potential contamination with nitrosamines has been carried out in accordance with the harmonized implementation of Swissmedic in accordance with the EMA questionnaire (Questions and answers for marketing authorization holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products), although it is not a chemically synthesized or biological substance with chemically synthesized fragments, but a purely mineral compound. biological substance with chemically synthesized fragments, but a purely mineral-based active substance.

Nitrosamines are formed by the reaction of nitrites with secondary amines. External analyses in an accredited laboratory in accordance with ISO 17025 have shown that, with the exception of nitrite curing salt, no nitrites could be detected in the evaporated salts (< 0.03 mg/kg).

SCHWEIZER SALINEN AG



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